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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,278	02/10/2004	Bruce R. Buchanan	HO-P02739US1	1234

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EXAMINER	
OMOSEWO, OLUBUSOLA	
ART UNIT	PAPER NUMBER
2168	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/775,278	BUCHANAN ET AL.	
	Examiner	Art Unit	
	OLUBUSOLA ONI	2168	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/12/2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to communications: Amendment filed on 01/12/2007

2. Claims 1,16, 27, 42, 54, 56, 58, 59, 61, 62, 63, 66, 67 and 83 have been amended.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-98 are rejected under 35 U.S.C. 102(e) as being anticipated by Rzasa et al.(Patent No: U.S 6,771, 369) hereinafter Rzasa

For claim 1, Rzasa teaches "data comprising at least one library of uniquely identifiable information for finished pharmaceutical dosage forms, said at least one library having uniquely identifiable information for finished pharmaceutical dosage forms manufactured by more than one manufacturer" (Col. 4, lines 44-67, Col. 6, lines 11-47);
"a central facility to house said data and to receive and/or transfer information to or from at least one user"(Col. 5, lines 35-44, Col. 7, lines 5-51, Col. 8, lines 38-55, Col. 10, lines 3-28).
"a communication link between said central facility and said user"(Col. 9, lines 20-33)
"wherein said data comprises analytical instrument data for at least two analytical instruments manufactured to have the same analytical response for a given measurement" (Col. 9, lines 20- Col. 10, lines 1-28 &fig. 4)

For claim 2, Rzasa teaches "further comprising at least one satellite instrument at a local testing center remote from said central facility"(Col. 9, lines 34-56)

For claim 3, Rzasa teaches "wherein the local testing center is located at a site in the supply chain of said pharmaceutical material"(Col. 10, lines 29-42)

For claim 4, Rzasa teaches "wherein said site is selected from the group consisting of pharmaceutical manufacturers, drug distribution centers, drug repackaging facilities, ports-of-entry, customs facilities, import facilities, mail facilities, government centers,

regulatory centers, pharmacies, hospitals, dispensaries, clinics, assisted-living facilities, and any combination thereof"(Col. 10, lines 29-42)

For claim 5, Rzasa teaches "wherein said at least one library comprises data collected from forensic methods selected from the group consisting of near-infrared spectroscopy, infrared spectroscopy, UV-VIS spectroscopy, fluorescence spectroscopy, phosphorescence spectroscopy, Raman spectroscopy, microwave spectroscopy, photo-acoustic spectroscopy, X-ray spectroscopy, chemical imaging, and any combination thereof"(Col. 9, lines 34-56)

For claim 6, Rzasa teaches "wherein said at least one library comprises data selected from the group consisting of images of products, packaging attributes, labeling attributes, product codes, lot numbers, expiration dates, track and trace data, and any combination thereof"(Col. 4, lines 1-15, Col. 6, lines 11-47)

For claim 7, Rzasa teaches "wherein the communication link comprises an internet link"(Col. 9, lines 20-33)

For claim 8, Rzasa teaches "wherein the database system further comprises a library of analytical information of known counterfeit finished pharmaceutical dosage forms"(Col. 4, lines 44-67, Col. 6, lines 11-47)

For claim 9, Rzasa teaches "wherein the pharmaceutical material comprises a finished pharmaceutical dosage form selected from the group consisting of oral dosage forms, injectables, inhalants, intravenous solutions, transdermals, suppositories, ophthalmics, and combinations thereof"(Col. 2, lines 38-60)

For claim 10, Rzasa teaches "wherein said at least one library is a validated library"(Col. 1, lines 55-67, Col. 2, lines 12-37, Col. 3, lines 5-28, Col. 5, lines 55-67)

For claim 11, Rzasa teaches "wherein said at least one library is an updated library"(Col. 7, lines 5-40)

For claim 12, Rzasa teaches "wherein the database system is a global database system" (Col. 5, lines 35-54, Col. 7, lines 5-40, Col. 10, lines 3-28)

For claim 13, Rzasa teaches "wherein said database is maintained and managed by an entity distinct from said at least one user"(Col. 7, lines 5-40)

For claim 14, Rzasa teaches "wherein said data comprising at least one library comprises a plurality of libraries"(Col. 4, lines1-15, Col. 6, lines 11-47)

For claim 15, Rzasa teaches "wherein said central facility transfers data to said at least one user"(Col. 8, lines 56-Col. 9, lines 1-19)

For claims 16, 27, 42, 54, 56, 58, 59, 61, 62, 63, 66, 67 and 83, these claims are rejected on grounds corresponding to the arguments given above for rejected claim 1 and is similarly rejected.

For claims 17, 36, 48, 64, 76 and 92 these claims are rejected on grounds corresponding to the arguments given above for rejected claim 5 and are similarly rejected.

For claim 18, 37, 49, 77 and 93 these claims are rejected on grounds corresponding to the arguments given above for rejected claim 6 and are similarly rejected.

For Claim 19, Rzasa teaches "further comprising at least one satellite instrument at a local testing center remote from said central facility wherein said local testing center is located at a site in the supply chain of said pharmaceutical material" (Col. 9, lines 34-56, Col. 10, lines 29-42)

For claims 20, 74 and 90 these claims are rejected on grounds corresponding to the arguments given above for rejected claim 4 and are similarly rejected.

For claims 21, 38, 50, 78 and 94, these claims are rejected on grounds corresponding to the arguments given above for rejected claim 10 and are similarly rejected.

For claims 22, 39, 51, 79 and 95 these claims are rejected on grounds corresponding to the arguments given above for rejected claim 11 and are similarly rejected.

For claims 23, 40, 52, 80 and 96 these claims are rejected on grounds corresponding to the arguments given above for rejected claim 12 and are similarly rejected.

For claims 24, 41, 53, 55, 57, 60, 65, 82 and 98 these claims are rejected on grounds corresponding to the arguments given above for rejected claim 13 and are similarly rejected.

For claim 25, 81, 97 these claims are rejected on grounds corresponding to the arguments given above for rejected claim 14 and are similarly rejected.

For claim 26, this claim is rejected on grounds corresponding to the arguments given above for rejected claim 15 and is similarly rejected.

For claim 28, Rzasa teaches "wherein said at least one library is constructed from manufacturer-verified pharmaceutical material" (Col. 2, lines 38-60, Col. 10, lines 29-42)

For claim 29, Rzasa teaches "the step of supplementing the library with the analytical data collected for said sample at said remote location"(Col. 2, lines 38-67)

For claim 30, Rzasa teaches "wherein the method further comprises the step of supplementing the library with the analytical data collected for the sample at said remote location"(Col. 4, lines 1-15, Col. 6, lines 11-47)

For claim 31, Rzasa teaches "the step of collecting assay data relating to said sample" (Col. 2, lines 38-67)

For claim 32, Rzasa teaches "wherein said sample comprises a pharmaceutical ingredient"(Col. 2, lines 38-67)

For claim 33, Rzasa teaches "wherein said pharmaceutical ingredient comprises a pharmaceutical ingredient selected from the group consisting of active pharmaceutical ingredients, excipients, pharmaceutical raw materials, pharmaceutical mixtures, pharmaceutical packaging materials, and combinations thereof" (Col. 4, lines 44-67, Col. 6, lines 11-47)

For claim 34, Rzasa teaches "wherein said pharmaceutical ingredient is a pharmaceutical mixture"(Col. 2, lines 38-60)

For claim 35, Rzasa teaches "wherein said pharmaceutical mixture is a granulation"(Col. 2, lines 38-60)

For claims 43, 68, 84 these claims are rejected on grounds corresponding to the arguments given above for rejected claim 9 and are similarly rejected.

For claim 44, Rzasa teaches "the step of processing said data for said finished pharmaceutical dosage form"(Col. 4, lines 44-67, Col. 6, lines 11-47)

For claims 45, 72, 88 these claims are rejected on grounds corresponding to the arguments given above for rejected claim 29 and are similarly rejected.

For claim 46, Rzasa teaches "wherein the method further comprises the step of supplementing the library with the analytical data collected for the sample at said remote location"(Col. 4, lines 1-15, Col. 6, lines 11-47)

For claims 47 and 75 these claims are rejected on grounds corresponding to the arguments given above for rejected claim 31 and are similarly rejected.

For claims 69,85 these claims are rejected on grounds corresponding to the arguments given above for rejected claim 8 and are similarly rejected.

For claim 70, Rzasa teaches "the step of correlating said data for said pharmaceutical sample to complimentary data for said sample"(Col. 9, lines 34-56)

For claim 71, Rzasa teaches "the step of processing said data for said sample"(Col. 9, lines 34-56)

For claim 72, this claim is rejected on grounds corresponding to the arguments given above for rejected claim 29 and is similarly rejected.

For claim 73, Rzasa teaches "wherein the method further comprises the step of supplementing the at least one library with data collected for the sample at said remote location"(Col. 4, lines 1-15, Col. 6, lines 11-67)

For claim 86, Rzasa teaches "the step of correlating said data for said pharmaceutical sample to complimentary data for said sample"(Col. 9, lines 34-56)

For claim 87, Rzasa teaches "the step of processing said data for said finished pharmaceutical dosage form"(Col. 4, lines 44-67, Col. 6, lines 11-47)

For claim 89, Rzasa teaches "wherein the method further comprises the step of supplementing the library with the analytical data collected for the sample at said remote location"(Col. 4, lines 1-15, Col. 6, lines 11-47)

For claim 91, Rzasa teaches "the step of collecting assay data for said sample of

finished pharmaceutical dosage form " (Col. 2, lines 38-67, Col. 4, lines 1-15, Col. 6, lines 11-47)

Response to Argument

5. Applicant's argument filed January 12, 2007 has been fully considered but they are not persuasive. The examiner respectfully traverses applicant's arguments.

As per claim 1, applicant argued that Rzasa doe not teach "wherein said data comprises analytical instrument data for at least two analytical instruments manufactured to have the same analytical response for a given measurement" as amended by applicant. However, at Col. 9, lines 20- Col. 10, lines 1-28 &fig. 4, Rzasa teaches drug information such as, chemical fingerprints and identifying information corresponding to the drugs available in a pharmacy are scanned into the RXSpec data library within the data storage and analysis unit. However, for comparison purposes data obtained from scanning the bar code label 534 of the RXSpec system's (first analytical instrument manufactured) are sent back to the data storage and analysis unit for a comparison of the drug information (second analytical instrument manufactured), after which the data storage and analysis unit sends a message back to the RXSpec system's main housing with the result, which determines either a similarity or no similarity between the two (the drug information in the data storage and analysis unit and scanned drug information from the RXSpec system's) equivalent to (analytical response measurement). Therefore, applicant's invention functions in the same way as Rzasa's i.e. two analytical

instruments to have the same analytical response for a given measurement. Thus, the claimed invention is not distinct over the prior art of Rzasa as argued by the applicant.

CONCLUSION

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to OLUBUSOLA ONI whose telephone number is 571-272-2738. The examiner can normally be reached on 10.00-6.30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, TIM VO can be reached on 571-272-3642. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner
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